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Issues and Challenges in Selecting a Vaccine Manufacturing Platform:

INTERNATIONAL VACCINE TECHNOLOGY WORKSHOP

HYDERABAD, INDIA

PRTM

Management Consultants

Where Innovation Operates

Emerging economies desire regional, independent, and sustainable vaccine production capacity

Global Action Plan for Pandemic Influenza vaccine calls for sustainable production capacity and capability worldwide

Solutions beyond influenza , to other public health threats

Address gaps in vaccine development and production

Few stakeholders have wherewithal to accomplish objectives alone

- Mutual roles and responsibilities

Solutions must leverage resources effectively

- Existing and new

Policy options will drive technology options

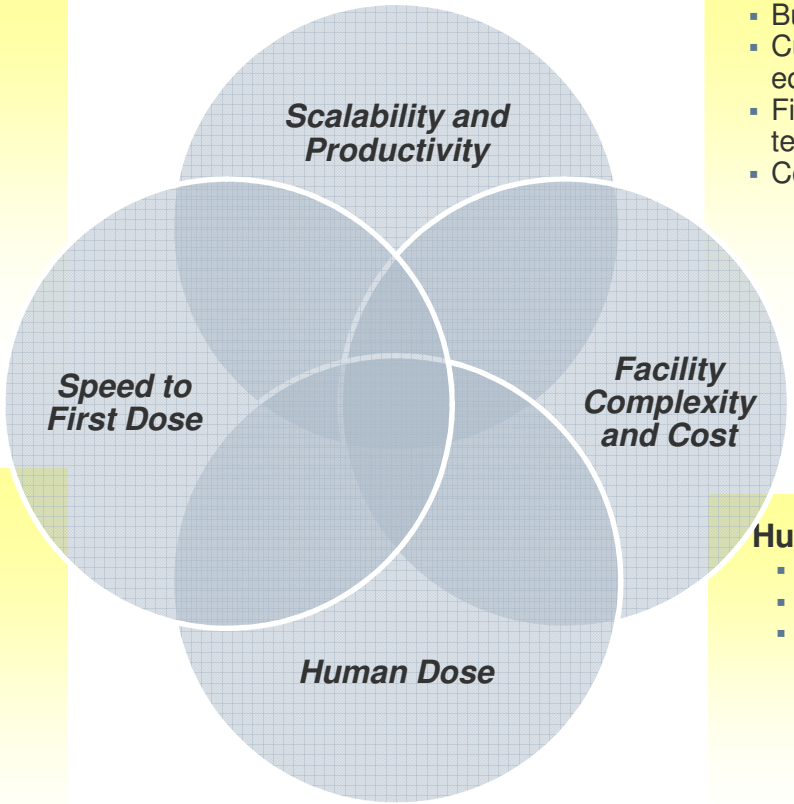
- Short-, medium-, and long-term

A best-fit strategy for each region should follow a decision framework to balance equities of all stakeholders

Manufacturing platform selection begins with consideration of the manufacturing landscape

Scalability
- Dose requirements
- Standards of control
- Production capacity
- Delivery devices

Facility Complexity and Cost
- Build new, retrofit, outsource
- Custom or standard equipment
- Fixed or single-use technology
- Cost of excess capacity



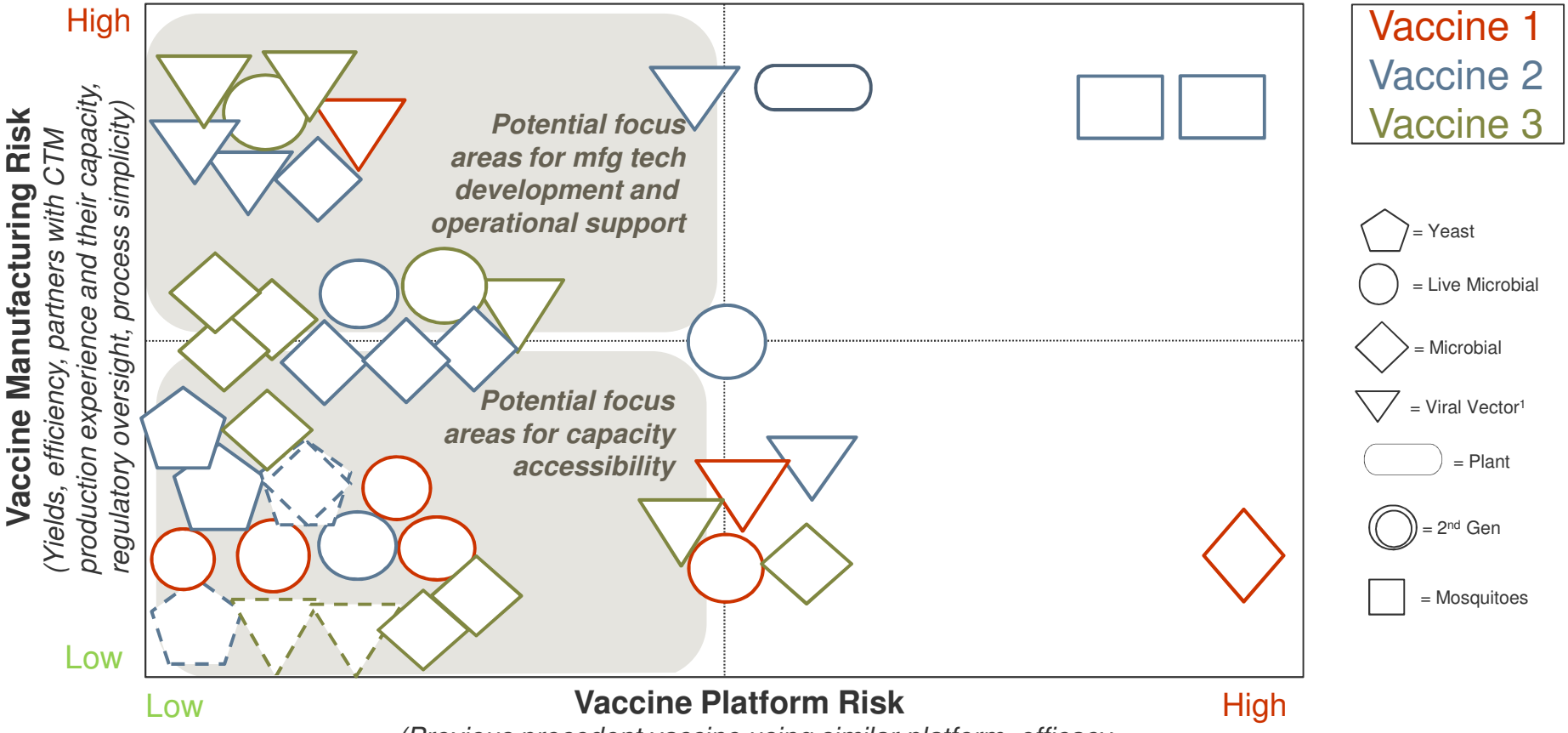
Speed to First Dose
- Primary isolate to first dose
- Reagent development and release testing

Human Dose
- Dosing
- Adjuvant?
- Formulation process and scale

Many factors beyond global capacity, cost, and speed will drive solution selection

Risk Assessment is important in any Vaccine Manufacturing Landscape Assessment

Comparison of vaccine risk with manufacturing risk highlights areas of potential investment benefit

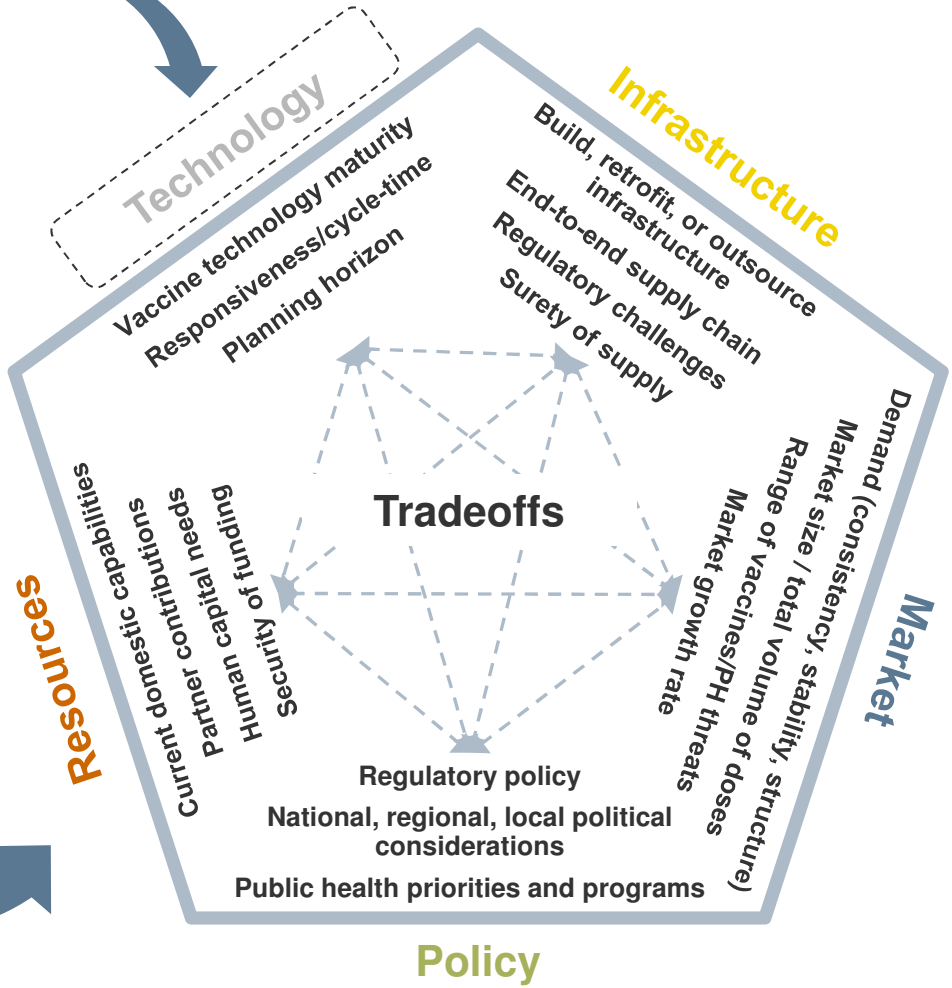


Manufacturing platform selection within a broader framework must balance many regional and national requirements

Technology is just one element in an ideal manufacturing strategy

In fact, <u>many</u> factors should influence platform selection to best…

- *Leverage existing resources*
- *Define roles & responsibilities of stakeholders*
- *Partnership opportunities and tradeoffs*



A best-fit manufacturing strategy should evaluate scenarios against locally important factors

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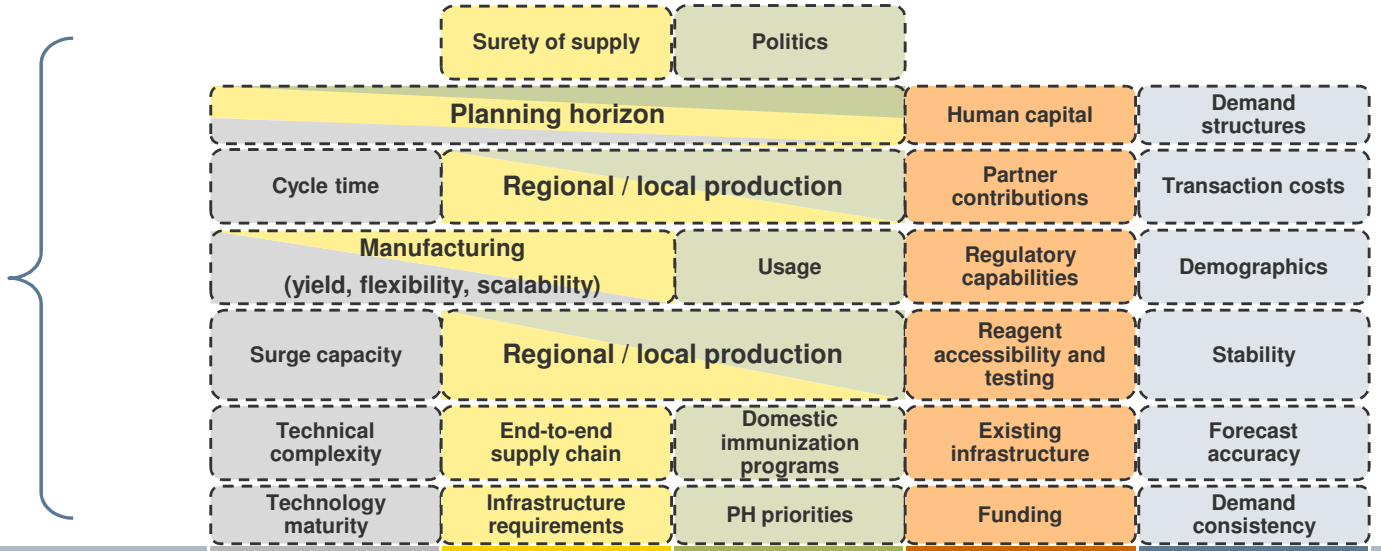


ILLUSTRATIVE

Scenario	Technology	Infrastructure	Policy	Resources	Market	∑
A	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Risk, Benefit Cost, Time
B	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Risk, Benefit Cost, Time
C	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Scale 1-5	Risk, Benefit Cost, Time

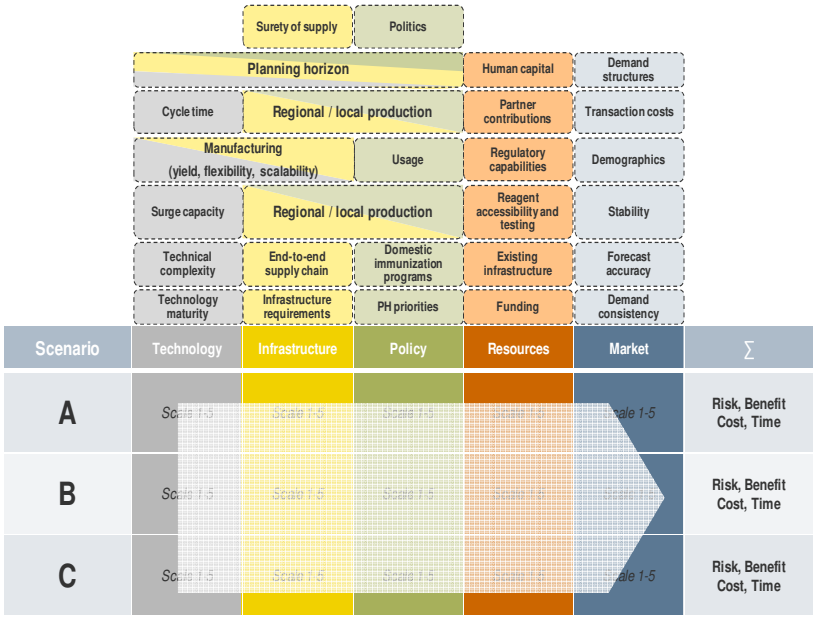
Evaluate potential costs, volumes, partners, and technical risk for each scenario (for each country)

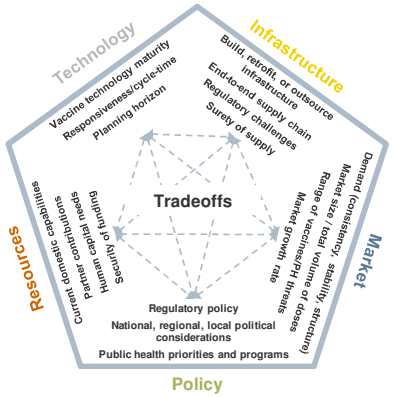
Strategic balance of policy and partnership aspirations with technical factors will ultimately yield an effective solution

Evaluate respective drivers important to regional stakeholders

Determine balance that meets all stakeholder requirements (Risk and return will vary by scenario)

Tailor manufacturing strategy to fit scenario





Risk, Benefit, Cost, Time

Comprehensive Manufacturing Strategy:

1. Production technology & facilities
2. E2E supply chain
3. Role of strategic partners
4. Organization/decision making
5. IT/information management

Balancing these factors will enable decision-makers to develop implementable strategies with chosen partners

The time is right to develop comprehensive, regional vaccine production strategies

Not simply a "technology problem"

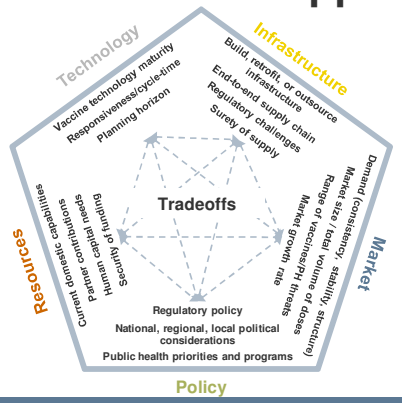
Unprecedented level of awareness and engagement

- Governments, NGOs, MNCs, Public Health professionals

Collaboration is absolutely essential

- Balance equities fairly
- No 'perfect' solution

Regional stakeholders could follow such an approach to develop and implement their own unique strategies



Achieving the Goal: Regional, Independent, Sustainable Vaccine Production Capacity

Thank you!
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Appendix

Challenges for Next Generation Flu Vaccines Manufacture

Demonstration of experience with sufficient number of isolates

Manufacturing consistency—variability due to new proteins/sequences

Downstream processing—can it be consistent for all isolates?

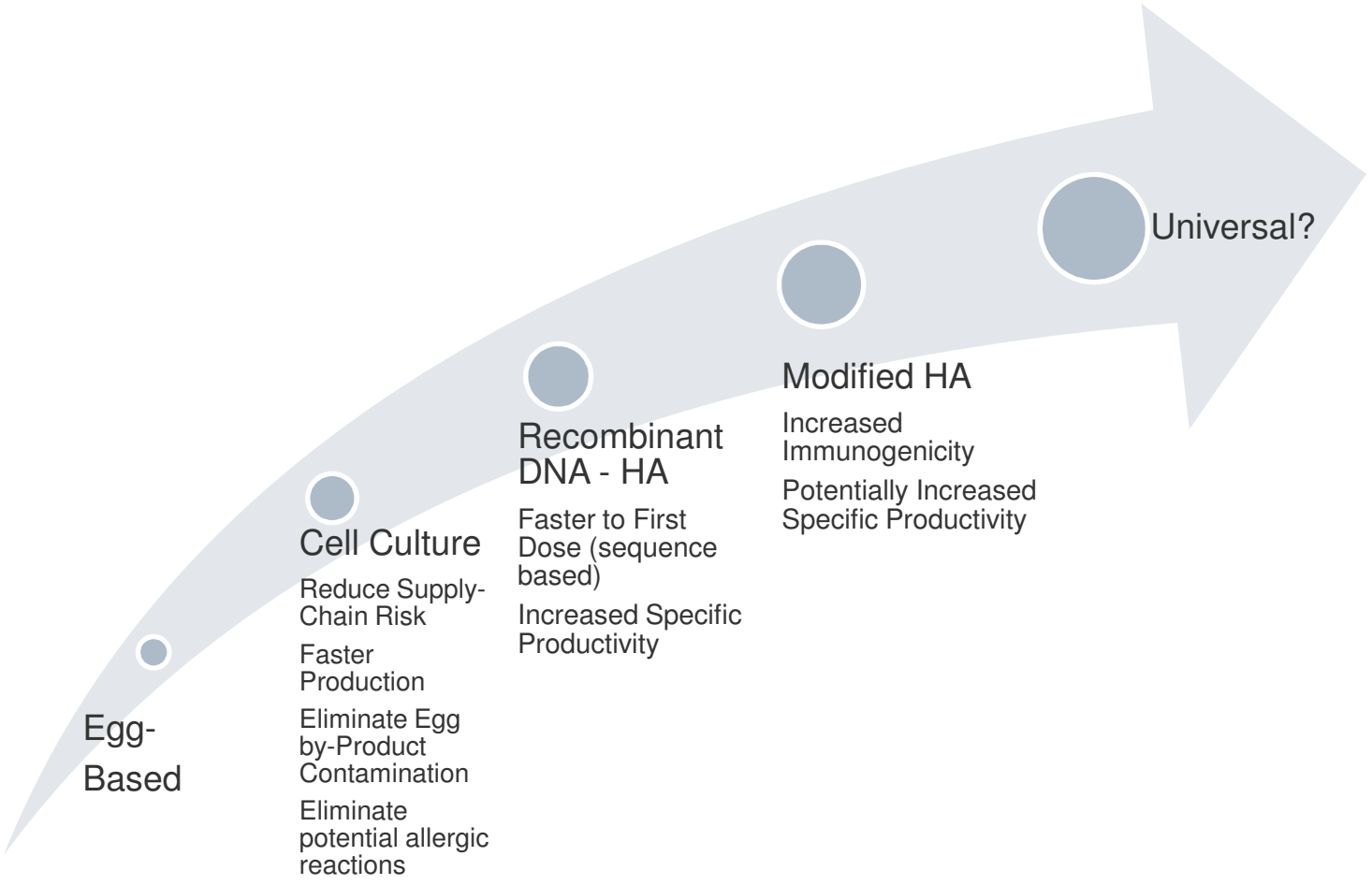
Available technology and infrastructure for manufacturing

Availability of reagents for product testing

Potency assays development

Process validation for seasonal manufacture

Flu Vaccine Product and Manufacturing Technology Evolution



Strategies for Next Generation Influenza Vaccine

Develop agreed critical path definitions from isolate to final delivery

Target each component for improvements – it's not just manufacturing

Potential trade-off in a next generation vaccine

- Speed
- COGS - including delivery device
- Capacity – can it be easily transferred, is there available capacity
- Delivery – can it be formulated to be stored at room temperature
- Consistency – can the process simple and robust

There are likely multiple right answers